

## **ABSTRACT**

The invention is directed to a method of detecting a malignancy or a pre-malignant lesion in breast or other tissue, or a pathologic condition, by detecting the presence of single-chain or two-chain forms of matriptase in the tissue. The invention is further directed to a 5 method of treating malignancies, which have the phenotype of matriptase production by administering a tumor formation inhibiting effective amount of concentrate of Bowman-Birk inhibitor (BBIC), or other matriptase inhibitor. The invention also is directed to nucleic acids encoding a matriptase protein or fragments thereof, and their use for structure elucidation and modeling to identify other inhibitors of matriptase, as well as to methods of identifying 10 matriptase modulating agents, including activators and inhibitors.

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